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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/735,073	12/12/2000	Shirin Asina	ROGO-214.2-Cont	3402

24972 7590 02/26/2002
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/18 5073

Applicant(s)

Asina et al

Examiner

Haff

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12/12/00
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-53 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-53 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2 filed 12/12/00
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Claims examined on the merits are 1-53 which are all claims in the application.

The disclosure is objected to because of the following informalities: the specification does not contain a heading designating a
5 summary of the invention. On page 5, between lines 13 and 14, there should be inserted -- SUMMARY OF THE INVENTION --.

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C.
112:

10 The specification shall contain a written description of the
 invention, and of the manner and process of making and using
 it, in such full, clear, concise, and exact terms as to enable
 any person skilled in the art to which it pertains, or with
15 which it is most nearly connected, to make and use the same
 and shall set forth the best mode contemplated by the inventor
 of carrying out his invention.

Claims 1-53 are rejected under 35 U.S.C. 112, first paragraph,
because the specification, while being enabling for restricting cell
proliferation by entrapping cancer cells such that the cells have limited
20 volume for growth, and proliferation is stopped when cell growth causes
the number of cells produced to fill the volume such that there is no
more room for additional cells, does not reasonably provide enablement
for other embodiments of restricting that can be within the scope of the
claims. The specification does not enable any person skilled in the art
25 to which it pertains, or with which it is most nearly connected, to make
and use the invention commensurate in scope with these claims.

The specification describes no other way of restricting cell
proliferation, and the claims and specification must be commensurate in
scope.

The following is a quotation of the second paragraph of 35
U.S.C. 112:

5 The specification shall conclude with one or more claims
 particularly pointing out and distinctly claiming the subject
 matter which the applicant regards as his invention.

Claims 1-53 are rejected under 35 U.S.C. 112, second paragraph, as
being indefinite for failing to particularly point out and distinctly
claim the subject matter which applicant regards as the invention.

10 In all claims, the requirement for restricting proliferation of
cancer cells and/or for restricted cancer cells is unclear in that the
way in which the cells are restricted has not been set forth. The
specification discloses only restricting of cell proliferation as set
forth above as being enabled, and this form of restricting the cells
15 should be required in the claims to be clear.

Bridging lines 2 and 3 of claim 1 and where recited in other claims,
"proliferation-restrictive, selectively-permeable structure" is uncertain
as to meaning and scope. How the structure restricts proliferation has
not been specified, and structures that restrict proliferation and do not
20 is uncertain.

Bridging lines 3 and 4 of claim 1 and where recited in other claims,
"time sufficient to restrict the proliferation" is uncertain as to
sufficient time since the phenomena that occurs in the structure when
restriction of proliferation occurs has not be specified.

25 Claims 1 and 9 are unclear as to what contains the material that
suppresses cancer cell proliferation. Is the material in the medium
recovered or some other place. This also applies to claims 2 and 10,

since it is unclear as to which molecular weight fraction contains the cancer cell suppressing material and is recovered.

Claim 2 is confusing by not having antecedent basis for "said filter". Claim 1 does not require a filter.

5 In claim 20, line 1, and where recited in other claims, "type of" and in claim 21, line 1, and where recited in other claims, "same type" are uncertain as to meaning and scope. When a material is close enough in characteristics to be a type of material or the same type of material is relative and subjective.

10 Claim 51 is unclear as to whether or not the structure contains cells. If cells are not in the structure they cannot be restricted.

Claim 52 is unclear by the preamble requiring producing a structure whereas in the body of the claim, cells are added to restrictive matter to produce a structure, and culturing is carried out to restrict the
15 cells. The preamble should require producing a structure containing restricted cells. In line 3, the meaning and scope of "matter" is uncertain. Moreover, merely contacting cells with matter will not provide a structure in which cells can be restricted. The cells would have to be entrapped such that there is limited volume for proliferation
20 to occur as set forth above. In line 3, there is not clear antecedent basis for "the structures". Plural structures have not been previously required.

In claims 1 and 52 and in other claims that require culturing a structure or structures, the claims are unclear in that cells and not
25 structures are cultured. Structures cannot be cultured.

Claim 53 is unclear by restricting cancer cells with a structure, and then culturing until the cells are restricted. If the cells have been already restricted with the structure, why is culturing needed for restricting?

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-31, 33-39 and 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Jain et al (WO 97/36495).

Claim 29 and claims dependent thereon are drawn to suppressing
15 proliferation of cancer cells by administering to a subject a proliferation-restrictive selectively permeable structure containing restricted cancer cells that due to restriction produce a substance that suppresses cancer cell proliferation.

Claim 51 is drawn to a composition containing the structure, claim
20 52 is drawn to preparing the structure and claim 53 is drawn to a method of increasing production of a material that suppresses cancer cells by culturing cancer cells in a structure until the cells are restricted and produce more of the material.

Jain et al disclose encapsulating cancer cells in capsules such that
25 proliferation of the cells is restricted during growth and the restricted cancer cells produce more of a cancer suppressing substance than when not

restricted. The encapsulated cells can be implanted in a subject to produce the substance and suppress cancer in the subject.

Jain et al disclose the methods and composition of the present claims.

5 Jain et al is a reference since parent application 08/745,063 is not enabling for the claimed invention, and Jain et al was published more than one year before filing the instant application.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a
15 person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the
20 contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

25 Claims 1, 3-9, 11-18, 32, 40, 41 and 44-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (WO 97/36495).

Claims 1, 3-19, 11-18, 40, 41 and 44-50 are drawn to a composition for suppressing cancer cells, a method of making the composition and to a method of using the composition to suppress cancer cells in a subject

wherein the composition is produced by culturing in a medium a proliferation-restrictive selectively permeable structure containing entrapped cancer cells for a time sufficient to restrict proliferation of the cells so that the cells produce a material that suppresses
5 proliferation of cancer cells and recovering the medium.

Jain et al (WO 97/36495) is described above. Jain et al further disclose (page 16, lines 14-16) that the encapsulated cells can be cultured *in vitro* to produce diffusible products that move into the culture medium where the products can be collected.

10 In view of this *in vitro* culturing disclosed by Jain et al, it would have been obvious to culture the encapsulated cancer cells *in vitro*, and recover the medium containing the cancer cell suppressing material. Using a human as the subject of Jain et al as in claims 32 and 41 would have been merely a matter of selecting the desired subject to be treated,
15 and it would have been obvious to treat a human for the same reason any other subject is treated.

Claims 19-28, 30, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al (WO 97/36495) in view of Jain et al (5,643,569).

20 The claims require a method of suppressing cancer cells in a subject like claim 29 described above, except that the cancer cells restricted are from an individual or a species different from the subject.

Jain et al (WO 97/36495) is described above.

Jain et al (5,643,569) disclose encapsulating cells that produce a
25 substance, and the encapsulated cells can be implanted in a subject for

the substance to be produced to provide a therapeutic affect. The encapsulated cells implanted can be different from the subject (col 9, lines 1-12). Mice can be the recipient and a rat the donor.

It would have been a matter of obvious choice to use as the cancer
5 cells restricted in Jain et al (WO 97/36495) cancer cells that are from a species or individual different from the subject in which cancer cells are being suppressed as suggested Jain et al (5,643,569) using mice as a recipient and a rat as a donor.

The nonstatutory double patenting rejection is based on a judicially
10 created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645
15 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37
CFR 1.321(c) may be used to overcome an actual or provisional rejection
20 based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record
may sign a terminal disclaimer. A terminal disclaimer signed by the
25 assignee must fully comply with 37 CFR 3.73(b).

Claims 1-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,224,912 B1. Although the conflicting claims are not
30 identical, they are not patentably distinct from each other because the presently claimed invention would have been obvious from the claims of the patent that require restricting cancer cells in the same type of way presently claimed.

Claims 29-39 and 51-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,888,497. Although the conflicting claims are not identical, they are not patentably distinct from each other
5 because the claimed methods involving restricting cancer to produce a cancer cell suppressing material would have been obvious from the claims of the patent that require restricting cancer cells to produce a material that suppresses cancer cells.

Claims 1, 3-9, 11-18, 40, 41 and 44-50 are rejected under the
10 judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,888,497 in view of Jain et al (WO 97/36495).

It would have been obvious to culture in a medium *in vitro* the entrapped cancer cells that produce a cancer suppressing material of the
15 patent claims to allow the cancer suppressing material to diffuse into the medium and recover the medium as suggested by Jain et al (WO 97/36495) as set forth above when rejecting these claims.

Claims 42 and 43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-
20 8 of U.S. Patent No. 5,888,497 in view of Jain et al (WO 97/36495) and Jain et al (5,643,569).

When carrying out the claims of the patent as set forth above in view of Jain et al (WO 97/36495), it would have been obvious to restrict cancer cells of a species different from the subject in view of Jain et
25 al (5,643,569) for reasons set forth above when rejecting claims 42 and 43.

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Claims 19-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,888,497 in view of Jain et al (5,643,497).

It would have been obvious to select the restricted cancer cells of the patent claims from a species different from the subject being treated in view of Jain et al (5,643,497) for reasons set forth above when rejecting claims 19-28.

Claims 2 and 10 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

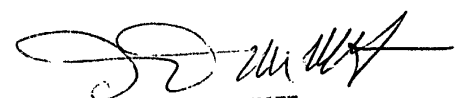
If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DMN
2/22/02


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651